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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/527,559	08/15/2005	Richard H. Ebright	744-48 PCT/US	7319
23280 7590 10/07/2010 Davidson, Davidson & Kappel, LLC 485 7th Avenue 14th Floor New York, NY 10018				
EXAMINER VOGEL, NANCY TREPTOW				
ART UNIT		PAPER NUMBER		
1636				
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/527,559

**Applicant(s)**

EBRIGHT, RICHARD H.

**Examiner**

NANCY VOGEL

**Art Unit**

1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 07 September 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1, 4-6 and 9-13 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 4-6 and 9-13 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB-08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

Claims 1, 4-6, 9-13 are pending in the case.

Any rejection of record in the previous action not addressed in this office action is withdrawn.

The following are new rejections not necessitated by applicant's amendments.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 5, 6, 10, are rejected under 35 U.S.C. 102(b) as being anticipated by Sonenshein et al. (J. Bacteriol., Vol. 132, No. 1, 73-79, 1977).

Sonenshein et al. disclose a method of identifying an agent that binds to a bacterial RNAP homologous RNA exit channel amino-acid sequence in an *B. subtilis* bacterial RNAP, comprising the steps of preparing a reaction solution including the agent (lipiarmycin) to be tested and a bacterial RNAP that contains a bacterial RNAP homologous RNA-exit-channel amino-acid sequence, and detecting the presence of binding of the agent to the homologous bacterial RNAP RNA-exit-channel amino acid-sequence (see Fig. 2, Fig. 4). The detection of inhibition of RNA polymerase function constitutes a method of detecting the binding the agent to the RNAP. The reference

also teaches a further step of detecting the presence and concentration dependence of binding of the agent to a second bacterial RNAP that contains a derivative of a bacterial RNAP homologous RNA-exit-channel amino acid sequence having at least one substitution, insertion or deletion (see Fig. 4).

Claims 1, 4, are rejected under 35 U.S.C. 102(b) as being anticipated by Sergio et al. (J. Antibiotic., Vol. 28, No. 7, 543-549, 1975)

Sergio et al. disclose a method of identifying an agent that binds to a bacterial RNAP homologous RNA exit channel amino-acid sequence in an E. coli bacterial RNAP, comprising the steps of preparing a reaction solution including the agent (lipiarmycin) to be tested and a bacterial RNAP that contains a bacterial RNAP homologous RNA-exit-channel amino-acid sequence, and detecting the presence of binding of the agent to the homologous bacterial RNAP RNA-exit-channel amino acid-sequence (see Fig. 6). The detection of inhibition of RNA polymerase function constitutes a method of detecting the binding of the agent to the RNAP.

Claims 1, 4, 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Talpaert et al. (Bioch. Biophys. Res. Comm, 63(1):328-334).

Talpaert et al. disclose a method of identifying an agent that binds to a bacterial RNAP homologous RNA exit channel amino-acid sequence in an E. coli bacterial RNAP, comprising the steps of preparing a reaction solution including the agent (lipiarmycin) to be tested and a bacterial RNAP that contains a bacterial RNAP homologous RNA-exit-channel amino-acid sequence, and detecting the presence of binding of the agent to the homologous bacterial RNAP RNA-exit-channel amino acid-

sequence (see Fig. 2, 3). The detection of inhibition of RNA polymerase function constitutes a method of detecting the binding the agent to the RNAP. The reference further discloses comparison of at least one of the presence extent, concentration-dependence or kinetics of binding of the agent to bacterial RNAP, and at least one of the presence extent, concentration-dependence, or kinetics of binding of the agent to a eukaryotic RNAP (Fig. 1).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 12, 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Talpaert et al. (cited above) in view of Young et al. (US Patent 5,919,666).

Talpaert et al. disclose a method of identifying an agent that binds to a bacterial RNAP homologous RNA exit channel amino-acid sequence in an E. coli bacterial RNAP, comprising the steps of preparing a reaction solution including the agent (lipiarmycin) to be tested and a bacterial RNAP that contains a bacterial RNAP homologous RNA-exit-channel amino-acid sequence, and detecting the presence of binding of the agent to the homologous bacterial RNAP RNA-exit-channel amino acid-sequence (see Fig. 2, 3). The detection of inhibition of RNA polymerase function constitutes a method of detecting the binding the agent to the RNAP. The reference

further discloses comparison of at least one of the presence extent, concentration-dependence or kinetics of binding of the agent to bacterial RNAP, and at least one of the presence extent, concentration-dependence, or kinetics of binding of the agent to a eukaryotic RNAP (Fig. 1). The difference between the reference and the instant claims is that human RNAP or RNAPII is used as the eukaryotic RNAP for comparison. However, human RNAP and human RNAPII are known as disclosed in Young et al. (US Patent 5,919,666) (see col. 20-22, claims of Young et al.). As acknowledged in the reference and the instant specification, purified human RNA polymerase II was known in the art. It would have been obvious to have utilized any mammalian RNA polymerase, including human RNA polymerase II, in the method of Talpaert et al., since the importance of human RNA polymerase II in transcription in human cells was recognized in the art, as well as the importance of elucidation of antibiotic effects on human systems, such as transcription by RNA polymerase. One would have been motivated to use human RNA polymerase by the desire to identify the effect of any particular antibiotic on the human system of transcription, especially since antibiotics that affect human systems in the same way as bacterial systems, would not be acceptable for human treatment. Based upon the teachings of the cited references, the high skill of one of ordinary skill in the art, and absent evidence to the contrary, there would have been a reasonable expectation of success to result in the claimed invention.

Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sonenshein et al. (cited above) in view of Talpaert et al. or Sergio et al. (cited above).

Sonenshein et al. disclose a method of identifying an agent that binds to a bacterial RNAP homologous RNA exit channel amino-acid sequence in an *B. subtilis* bacterial RNAP, comprising the steps of preparing a reaction solution including the agent (lipiarmycin) to be tested and a bacterial RNAP that contains a bacterial RNAP homologous RNA-exit-channel amino-acid sequence, and detecting the presence of binding of the agent to the homologous bacterial RNAP RNA-exit-channel amino acid-sequence (see Fig. 2, Fig. 4). The detection of inhibition of RNA polymerase function constitutes a method of detecting the binding the agent to the RNAP. The reference also teaches a further step of detecting the presence and concentration dependence of binding of the agent to a second bacterial RNAP that contains a derivative of a bacterial RNAP homologous RNA-exit-channel amino acid sequence having at least one substitution, insertion or deletion (see Fig. 4).

The difference between the reference and the instant claim is that *E. coli*, rather than *B. subtilis*, derivatives having at least one substitution, insertion or deletion in the RNAP homologous RNA-exit-channel amino acid sequence is used in the further method. However, Talpaert et al. and Sergio et al. each disclose methods of identifying an agent that binds to RNAP homologous RNA exit channel amino acid sequence in *E. coli* RNAP. It would have been obvious to have used *E. coli* RNAP in the method of Sonenshein et al., since *E. coli* RNAP is known to have homology to *B. subtilis* RNAP, and since mutants of each in the RNAP homologous RNA-exit-channel amino acid sequence would be expected to behave similarly. One would have been motivated to do so by the interest in the identification of agents and their mode of action useful

against *E. coli*, especially since it is a known pathogen. Based upon the teachings of the cited references, the high skill of one of ordinary skill in the art, and absent evidence to the contrary, there would have been a reasonable expectation of success to result in the claimed invention.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NANCY VOGEL whose telephone number is (571)272-0780. The examiner can normally be reached on 7:00 - 3:30, Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571) 272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



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/NANCY VOGEL/  
Primary Examiner, Art Unit 1636

NV  
9/26/10